

REMARKS

Consideration of this application in view of the above amendments and following remarks is respectfully requested. Claims 17-20, 55-56, 141-144, 147 and 150 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined disclosures of three references: U.S. Patent 3,123,077 to Alcamo, U.S. Patent 5,123,911 to Granger and U.S. Patent 5,931,855 to Buncke. Applicants respectfully but strenuously traverse the rejection. The following remarks provide a summary of the positions taken in the Office Action, and also provide Applicants' comments on those positions.

Applicants' invention of claim 18 recites that the claimed suture has barbs arranged in multiple spirals, where the spirally-arranged barbs have a spirality angle ranging from 5 to 25 degrees. This feature is not disclosed in any of the cited references. However, the Office Action points to the Figures of Alcamo as disclosing barbed sutures having a lot of barbs, and then makes the argument that one of ordinary skill in the art could have selected multiple sets of the barbs, where the barbs of each set are disposed in a spiral arrangement. While Applicants respectfully disagree that this view of Alcamo would ever occur to one of ordinary skill in the art, even with the best hindsight selection, it is hard to see how the spirality angle of Applicants' claimed invention could arise from the disclosure of Alcamo. However, the Office Action deals with this shortcoming in Alcamo by dismissing the feature, asserting that this undisclosed feature would be "an obvious design choice".

Applicants' invention of claim 17 recites that the claimed suture is attached to a needle, where the ratio of a) the diameter of the needle at the needle's thickest part to b) the diameter of the barbed suture, is about 3:1 or less. This feature is not disclosed in any of the cited references. However, the Office Action points to Granger, which does not mention barbed sutures at all, but instead discloses non-barbed sutures attached to needles, where the needle diameter and the suture diameter are equal. The Office Action makes the argument that it would therefore be obvious to attach a barbed suture to a needle. As for the relative sizes of a barbed suture and a needle diameter, the Office Action deals with this omission in Granger by taking the position that the selection would be "an obvious design choice".

Applicants' invention of claims 16 and 17 further recite that the barbs are in a staggered arrangement. To find this feature, the Office Action turns to yet another reference,

namely Buncke. At col. 8, lines 58-62, Buncke discloses a barbed suture (96) having barbs (98) in staggered positions. Noteworthy is that the barbs, while staggered, are all located in a single plane, which is outside the scope of Applicants' claimed invention.

Applicants note that the rejection in the Office Action relies heavily upon the position that features of Applicants' claims are obvious design choices. Presumably, a convincing showing that the "design choices" were "unobvious" would overcome this rejection. In this regard, the standard for whether a "design choice" is obvious or unobvious is missing from the Office Action, and Applicants are at a loss to know how to rebut this rejection.

In an attempt to move prosecution forward, Applicants note that the Office Action has twice pointed to *In re Aller*, and Applicants have looked at this decision, and the treatment thereof in the M.P.E.P., for guidance as to the Office Action's position. The M.P.E.P. provides a fair discussion of *In re Aller* in the context of a rejection under 35 U.S.C. § 103, in section 2144.05. It is there explained that generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%).

In response, Applicants would like to point out that there are important distinctions between the situation in *In re Aller* as discussed in the M.P.E.P., and the situation described in the Office Action regarding Applicants' claimed invention, where those distinctions render reliance on the holding of *In re Aller* inappropriate in the current situation.

In re Aller dealt with a chemical case where the prior art identified certain parameters, namely temperature and acid concentration. Not only did the prior art identify those parameters, the prior art also provided suitable/ desirable values for those parameters (100°C for the temperature, and 10% for the acid concentration). The issue in *In re Aller* was whether that prior art disclosure rendered *prima facie* obvious a claim wherein different conditions of

temperature and acid concentration were recited for an otherwise identical chemical process. The court, as reflected in the discussion of the M.P.E.P, concluded that indeed, the prior art disclosure did support a *prima facie* obviousness rejection under 35 U.S.C. §103 in that situation.

In contrast, Applicants' claimed invention is a mechanical invention, more specifically a barbed suture, which is outside the chemical arts. Furthermore, and very importantly, mention of spirally arranged barbs is nowhere to be found in the discussion in Alcamo. Looking at the Figures of Alcamo, none of those Figures looks like they have spirally-arranged barbs. Only with hindsight can one, perhaps, pick and choose among the barbs on the sutures of Alcamo, to discern a spiral pattern of barbs. Certainly the spiral pattern is not "obvious" from looking at any of the Alcamo figures. Thus, Applicants respectfully contend that Alcamo does not disclose the "general condition" of spirally arranged barbs in the sense that temperature and acid concentration were disclosed as "general conditions" in the prior art discussed in *In re Aller*. Furthermore, and perhaps most importantly, the "general condition" of if, and how, a spiral arrangement of barbs should be characterized, is nowhere to be found in Alcamo. For example, Alcamo does not provide or otherwise identify a "spirality angle" or any other characterizing feature of a set of spirally arranged barbs, as would be in analogy to the parameters of temperature and acid concentration as discussed in *In re Aller*. Unlike the situation addressed in *In re Aller*, Alcamo does not provide the "general condition" of spirality angle (or any equivalent thereof) which has been varied in Applicants' claims. Indeed, upon reading Alcamo, one of ordinary skill in the art would have no recognition that barbs should be arranged in a spiral pattern at all, much less that "spirality angle" was a parameter worth mentioning in regards to an arrangement of barbs. Therefore, the selection of "spirality angle" is not a design parameter that is taught or suggested by Alcamo, and the further recitation of a spirality range according to Applicant's claimed invention cannot be seen to be based on, or an optimization of, the disclosure of Alcamo. The current situation is therefore unlike the situation addressed in *In re Aller*, and the Office Action's reliance on that decision, for the purpose for which it has been relied, is inappropriate.

Applicants would like to make a related argument in regard to the Office Action's reliance on Granger. In this case, reliance on *In re Aller* is likewise inappropriate, although for a different reason than stated above in regards to Alcamo. In *In re Aller*, the claimed invention

and the prior art were both directed to the same process, differing in the selection of ranges for noted parameters. Likewise, in *Alcamo*, the subject of the prior art and the claimed invention is the same, namely, barbed sutures. However, Granger and Applicants' claimed invention are not directed to the same topic.

Applicants' invention is a barbed suture, while Granger discloses unbarbed sutures and nowhere mentions barbed sutures. As will be explained, there is a significant difference between these two systems (barbed and unbarbed sutures) as relates to needle selection, which renders reliance on *In re Aller* inappropriate. With unbarbed sutures, the suture is held in place by knots that are tied with the ends of the suture. The size of the needle that assists in delivering the unbarbed suture through the tissue has nothing to do with holding the suture in place; instead, the knots of those unbarbed sutures perform that function. In contrast, the reason that sutures have barbs is that the barbs interact with the neighboring tissue to thereby retain the suture in the tissue. The proximity of the tissue to the barbs is therefore a critical feature to the success of a barbed suture, and this proximity will be impacted by the size of the hole made when delivering the barbed suture to the tissue. This hole size is dependent on the size of the needle. Needle size therefore plays different roles when used with barbed vs. unbarbed sutures. This distinction is not recognized or suggested in Granger. The Office Action's reliance on Granger, which is directed solely to unbarbed sutures, is therefore not meaningful to the presently claimed invention. In analogy to the facts in *In re Aller* as discussed in the M.P.E.P., it would be as though the prior art and claimed invention were directed to different processes, albeit both processes were influenced by "temperature". That is the case we have here. The prior art and the claimed invention are directed to different "things", and the fact that both things happen to use a needle is just a coincidence. Thus, again, reliance on *In re Aller* is inappropriate.

In summary, Applicants respectfully contend that the Examiner has not, through the combination of the three cited references, set forth a proper rejection that the claimed invention is *prima facie* obvious. Accordingly, the burden is not on the Applicant to demonstrate that the recited values for the recited parameters provide a superior or unobvious performance property.

In view of these remarks, reconsideration and withdrawal of the rejection are earnestly requested. A good faith effort has been made to place this application in condition for allowance. However, should any further issue require attention prior to allowance, the Examiner is requested to contact the undersigned at (425) 831-3090 to resolve the same.

The Director is authorized to charge any additional fees due by way of this amendment, or credit any overpayment, to our Deposit Account No. 50-2574.

Respectfully submitted,

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